

Gregg L. Weiner
Stephen S. Rabinowitz
Fried, Frank, Harris, Shriver
& Jacobson LLP
One New York Plaza
New York, NY 10004
(212) 859-8000

Attorneys for Plaintiff
Keryx Biopharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.,

Plaintiff,

- against -

PANION & BF BIOTECH, INC.,

Defendant.

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ECF CASE
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07 Civ. 10376 (CSH)
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**PLAINTIFF’S REPLY MEMORANDUM OF LAW IN
SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION**

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PRELIMINARY STATEMENT

Defendant's opposition plays fast and loose with the facts, spinning a fanciful tale designed to muddy the waters and alarm the Court that harm will befall the public should the Court issue the requested preliminary injunctive relief. Panion's story, however, is demonstrably false, and only serves to reinforce the urgent need for Keryx to obtain each aspect of the preliminary injunctive relief it seeks.

First, Keryx's right to a preliminary injunction against Panion's threatened early termination of the License Agreement is uncontested. Panion does not challenge that (i) it first served notice of an alleged material breach on Keryx, in accordance with the License Agreement, on October 31, 2007, and (ii) the License Agreement plainly and unequivocally entitles Keryx to 90 days to cure any alleged breach. Notwithstanding this tacit concession, Panion still has not withdrawn its threat to terminate the agreement in advance of the January 29, 2008 cure deadline. Accordingly, Keryx's need for preliminary injunctive relief restraining Panion from prematurely issuing a notice terminating the License Agreement is clear.

Second, Panion's resort to scare tactics, through its false and slanderous statement that Keryx is attempting to develop and market drug products that are unsafe and are unauthorized by Panion, is recklessly irresponsible. Panion's charge, resting on nothing more than the speculation of a lay witness, is utterly unfounded. And as Panion's own testimony shows, Keryx's development work is being conducted under specifications that Panion expressly approved back in February 2007 (Cindy Chiang Decl. ¶ 9), and Keryx's clinical testing of the product is continuing under the supervision of the United States Food and Drug Administration (Bennett Reply Decl. ¶¶ 2, 3). In any event, Panion's allegations are wholly irrelevant to Keryx's motion, since none of the activities being conducted by Keryx's third party contractors will result in ferric citrate being supplied to Keryx. (Bennett Decl. ¶ 10) Yet Panion persists in seeking to interfere with these activities. In short, Panion should be restrained from interfering

with Keryx's vital development activities, which are expressly authorized under the License Agreement.

Third, the Court should grant Keryx's request for a preliminary injunction directing Panion to seek a routine extension of the deadline for responding to the pending Japanese Office Action. The extension is necessary and appropriate, and Panion has offered no sound reason for contending otherwise. Panion does not dispute that it delayed for over a month in providing the Japanese Office Action to Keryx; that its own counsel agreed to a three-month extension and then revoked that agreement solely on the basis of "unresolved issues between Keryx and Panion;" or that the routine extension sought by Keryx and its sublicensee, Japan Tobacco, likely will prove useful in responding fully to the Japanese Patent Office. Nor does Panion contend that it would be harmed in any way by seeking the requested and previously-agreed extension.

Rather, Panion's response is limited to its claim that Keryx will not be harmed by the lack of an extension. But the carefully worded declaration submitted by Panion is incomplete, and Panion ignores the loss of procedural rights that would inevitably flow from prematurely responding to the Japanese Patent Office on November 28th. See Reply Declaration of Eiichi Arai, ¶¶ 3, 4. Moreover, the alternative divisional application Panion relies on in an attempt to rescue Keryx from the loss of these critical procedural rights is insufficient, as the delay between requesting examination of the divisional application and receiving a first Office Action is unpredictable, and may last up to several years. (Id. ¶ 5) Thus, Panion's inexplicable refusal to seek the routine and previously-agreed three month extension of the pending deadline in Japan for responding to the Office Action in the original patent application threatens Keryx with immediate irreparable harm.

Accordingly, Keryx's motion for a preliminary injunction should be granted in all respects.

ARGUMENT

I. Keryx is Entitled To A Preliminary Injunction Restraining Panion From Serving, Before January 30, 2008, a Notice Terminating the License Agreement

Panion does not dispute that it was only on October 31, 2007 that it sent Keryx a notice in conformity with Section 12.3 of the License Agreement contending that Keryx's purchases of ferric citrate constituted a "material breach" of the Agreement. Accordingly, under the plain meaning of Section 12.3 of the Agreement, Keryx has ninety days from October 31, 2007 – i.e., until January 29, 2008 – to cure the alleged breach. Under New York law, which governs the Agreement, Keryx's right to a ninety-day cure period must be enforced as written. See SVS, Inc. v. Rabbit Ears Productions, Inc., No. 91 Civ. 6632, 1992 WL 91183 at *10 (S.D.N.Y. Dec. 12, 1992) ("Where the party asserting nonperformance does not give the defaulting party a chance to cure, the party asserting nonperformance cannot terminate the agreement."). Accordingly, Keryx is entitled to an injunction restraining Panion from issuing a notice of termination before January 30, 2008.¹

II. Keryx Is Entitled to a Preliminary Injunction Restraining Panion From Interfering With Keryx's Licensed Activities

Panion has not challenged that: Section 3.1 of the License Agreement expressly permits Keryx to use Panion-owned technology ("Licensor Know-How") "to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export the Product" (Weiss Decl., Exh. 1) (emphasis added); this broad grant of license rights necessarily includes work done to generate information that is needed for successful commercialization of ferric citrate as a pharmaceutical product (Bennett Decl. ¶¶ 8, 11); and these information-generating development activities do not result in Keryx being supplied with ferric citrate

¹ Panion does not contest Keryx's showing that severe and irreparable injury would flow from a premature notice terminating the License Agreement. Yet, Panion has refused to withdraw its threat to terminate the License Agreement before Keryx's time to cure the alleged breach expires.

(Bennett Decl. ¶ 10). Panion's tacit admissions – along with Keryx's undertaking to source future supplies of API in accordance with Section 7.7(b) -- should dispose of Panion's grounds for interfering with Keryx's contractors. But Panion is not so easily dissuaded.

Instead, Panion resorts to an egregious and irresponsible falsehood. Panion falsely claims – based solely on the unexplained, conclusory and self-serving assertion of a lay witness, Cindy Chiang – that ferric citrate produced for Keryx is substandard and harmful to human subjects. (Defendant's Memorandum of Law, ¶¶ 5-6; 19-20) This charge is wholly without basis.² Among other things, pharmaceutical development of ferric citrate is being conducted under the supervision of the FDA pursuant to revised specifications submitted to the FDA after Panion expressly approved them in February 2007. (Bennett Reply Decl. ¶ 8 & Exh. 6. See also Cindy Chiang Decl. ¶¶ 8, 9) The FDA has neither questioned nor objected to these revised specifications. (Bennett Reply Decl. ¶ 8 & Exh. 7)³

In all events, the work currently being done by Keryx's contractors will not result in supplying any ferric citrate to Keryx, and therefore, simply does not implicate Section 7.7(b). Because the contractors' ongoing activities for Keryx relate solely to licensed information-generating work, Panion has no basis for seeking to block those activities. Thus, Keryx likely will succeed on its claims that Panion has breached Keryx's broad rights under Section 3.1 of the

² The assertion that "Panion is the exclusive owner of ferric citrate API related to the '706 Patent" is plainly wrong and legally irrelevant. (Defendant's Memorandum of Law, p. 11.)

³ The contention that batch records for the four lots Keryx ordered in 2006 were not timely provided to Panion is a red herring. Nothing in the batch records is helpful to Panion's charges, and Panion does not deny that it was informed of Keryx's production of API before November 2006. Bennett Reply Decl. ¶ 9. See also Cindy Chiang Decl. ¶ 4 (admitting she knew of API production no later than January 2007). Panion's reference to results of toxicity testing in dogs is similarly misleading. Panion never tested its product in dogs, but only in rats. (Cullen Decl. ¶ 3) It was Keryx that proceeded to test ferric citrate in dogs as well, and the results of those tests have likewise been submitted to the FDA. (Id. ¶¶ 4-6)

License Agreement to develop the Product using “Licensor Know-How” and has tortiously interfered with Keryx’s existing business relations.

Second, it cannot seriously be disputed that interference with Keryx’s activities related to the development of the Product under the License Agreement will cause Keryx irreparable harm.⁴ The License Agreement is valuable to Keryx and a key part of its business. Preventing Keryx from working with its contractors (BRI, Biovectra and PharmPro) would hinder development of the product, undermine Keryx’s reputation in the Japanese market and elsewhere, disrupt Keryx’s existing business relationships with its contractors, and expose Keryx to vast damages which would not be readily ascertainable or likely to be recovered from a small company such as Panion. “Such interference with an ongoing business, particularly one involving a unique product and an exclusive licensing and distribution arrangement, risks irreparable injury and is enjoinable. . . .” U.S. Ice Cream Corp. v. Carvel Corp., 136 A.D. 2d 626, 628, 523 N.Y.S. 2d 869, 869 (2d Dep’t 1988). There is nothing speculative about this harm, and this showing more than satisfies the applicable preliminary injunction standard.⁵

Finally, the balance of harm tips decidedly in Keryx’s favor. Having conceded that it knew of Keryx’s activities in January 2007 (Cindy Chiang Decl. ¶ 4), Panion cannot plausibly

⁴ Panion does not meaningfully challenge the irreparable harm to Keryx, but rather disingenuously seeks to miscast the irreparable harm Keryx faces as “simply performing in accordance with the License Agreement.” (Defendant’s Memorandum of Law, p. 15.)

⁵ Neither of the two cases cited by Panion for the general rule that irreparable harm must be actual and imminent rather than remote or speculative, Rodriguez v. DeBuono, 175 F.3d 227 (2d Cir. 1999) (per curiam) and Shapiro v. Cadman Towers, Inc., 51 F.3d 328 (2d Cir. 1995), is to the contrary. See also Lentjes Bischoff GmbH v. Joy Envtl. Techs., Inc., 986 F. Supp. 183, 187 (S.D.N.Y. 1997) (“An injury is not ‘speculative’ simply because it is not certain to occur.”); Givenchy S.A. v. William Stuart Indust., No. 85 Civ. 9911, 1986 WL 3358, at *7 (S.D.N.Y. Mar. 10, 1986) (“Defendant’s assertion that [certain] communications have the potential to destroy W.S.I.’s business by destroying its relationship with key associates is entirely credible. This sort of damage to a business enterprise’s goodwill and business reputation has been recognized within this Circuit as a form of irreparable injury for which there is no adequate remedy at law.”)

contend that it will be harmed by an injunction preventing it from interfering with those activities pending a decision on the merits on the expedited schedule ordered by this Court.

III. Keryx is Entitled To A Preliminary Injunction Directing Panion To Request A Routine Extension Of The Time For Responding To The Japanese Patent Office

Panion rests its argument entirely on that portion of Section 8.1.1 of the License Agreement providing that "Licensee agrees that all final decisions regarding the preparation and prosecution of such patent applications and patents, reissues, reexaminations, interferences and opposition thereto shall be made by Licensors after consultation with Licensee." (Weiss Decl. Exh.1) But Panion ignores the further requirements that the Licensors shall:

"use reasonable efforts to prosecute the patent applications . . . regularly consult with Licensee and keep Licensee advised of the status of all patent applications and patents relating to the Patent Rights . . . provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence and submit to Licensors any proposed response thereto . . . [and] provide Licensee with sufficient time and opportunity, but in no event less than ten (10) days, to review, comment and consult on all proposed responses to patent office correspondence relating to such patent applications and patents." *Id.* (emphasis added)

These provisions require Panion to consult in good faith with Keryx concerning prosecution of the patent in Japan, and nothing authorizes Panion to refuse to consult with Keryx or to act irrationally or in bad faith in making any such final decision.⁶ But that is precisely Panion's course of dealing here.

⁶ See, e.g., *Tractebel Energy Mktg., Inc. v. AEP Power Mktg., Inc.*, 487 F.3d 89, 98 (2d Cir. 2007) ("Under New York law, a covenant of good faith and fair dealing is implicit in all contracts during the course of contract performance."); *Network Enterprises, Inc. v. APBA Offshore Productions, Inc.*, 427 F. Supp. 2d 463, 484 (S.D.N.Y. 2006) (Haight, J.) (same). This good faith requirement imposes on Panion the implied obligation not to "do anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract." *Dalton v. Educ. Testing Serv.*, 87 N.Y.2d 384, 389, 663 N.E. 2d 289, 291-92, (1995). Furthermore, even where the contract "contemplates the exercise of discretion, this pledge includes a promise not to act arbitrarily or irrationally in exercising that discretion." *Id.*

Among other things, it is undisputed that: (i) Panion did not notify Keryx until October 1, 2007, of the Japanese Patent office action it received on August 28, 2007, and an English translation was not provided until October 10th (Levine Decl. ¶¶ 7, 8)⁷; (ii) Panion initially agreed to the three-month extension and then did an about-face – blatantly asserting that it would not seek the extension “based on the unresolved issues between Keryx and Panion;”⁸ (Levine Decl. ¶ 13) (iii) Panion thereafter instructed its Japanese patent counsel not to communicate with Japan Tobacco’s counsel (Weiss Decl., Exh. 6); (iv) Japan Tobacco has identified 3000 references which may support issuance of a patent in Japan, the bulk of which need to be further analyzed (Levine Decl. ¶ 19 & Exh. 20); and (v) that Panion deems at least some of these references beneficial, and will include them in Panion’s proposed response to the Office Action (Levine Reply Decl. ¶ 8).⁹ Under these circumstances, Keryx has a clear claim for breach of Panion’s express and implied obligations under the parties’ contract.¹⁰

It is no answer to conclusorily assert, as Dr. Chan does, that “search for over six (6) weeks is unreasonable.” Chan Decl. ¶ 15. Review and analysis of over 3000 potentially helpful

⁷ Panion makes no effort to explain why it twice provided Keryx in September 2007 with an inaccurate and misleading docket report that failed to identify the August 28, 2007 Notice. Levine Reply Decl. ¶ 3.

⁸ Tellingly, Panion’s own docket report identifies February 28, 2008 as the absolute deadline for responding to the Japanese Patent Office, which further indicates that Panion had every intention of seeking the extension Keryx and Japan Tobacco are requesting here, before it determined to change course solely to obtain leverage over Keryx. (Levine Decl. ¶7 & Exh. 7 at 8)

⁹ Further evidencing its bad faith and in breach of the requirement in Section 8.1.1 that Keryx be afforded at least ten days to review and comment on any proposed response to the Office Action, Panion has refused Keryx’s request that it be informed of precisely which of the additional references it has shared with Panion will be included in Panion’s response to the Office Action. Levine Reply Decl. ¶ 9.

¹⁰ See Orange County Choppers, Inc. v. Olaes Enterprises, Inc., 497 F. Supp. 2d 541, 559 (S.D.N.Y. 2007) (withholding notice in order to coerce concessions under agreement violated duty to “use reasonable effort to notify [other party] in writing”); Edrei v. Copenhagen Handelsbank A/S, No. 91 Civ. 1860, 1991 WL 64201, at *8 (S.D.N.Y. April 18, 1991) (holding that if defendant negotiated in bad faith, it breached contractual best efforts obligation as well as implied commitment to deal with plaintiff in good faith).

publications self-evidently requires more than six weeks, and Panion has not stated any reason why an extension for this purpose would cause Panion any harm. Accordingly, Keryx will clearly succeed on the merits of claim that Panion breached Section 8.1.1 of the License Agreement.¹¹

Second, Keryx will be irreparably harmed if Panion continues to fail to comply with its duty under the License Agreement to cooperate with Keryx and its sublicensee in prosecuting the Japanese patent application. Successful prosecution of the Japanese patent application is critical to commercial development under the Japanese Sublicense. The failure to obtain the Japanese patent will threaten the value of the \$100 million Japanese Sublicense and damage Keryx's reputation in the pharmaceutical community. Such harm would not be capable of being remedied by a judgment for money damages and manifestly constitutes irreparable harm. See Danielson v. Local 275, Laborers Int'l Union of North America, AFL-CIO, 479 F.2d 1033, 1037 (2d Cir. 1973) (it is long-established that "[i]rreparable injury is suffered where monetary damages are difficult to ascertain or are inadequate").

Panion's attempt to dismiss the urgency of the Japanese Patent Prosecution is unconvincing and materially incomplete. While it is correct that new evidence or references may be submitted after responding to the Office Action, the applicant's unrestricted right to amend the claims will expire once that response is submitted. Moreover, reliance on the divisional application suffers from the flaw that it would cause delay that is "unpredictable, and may last up

¹¹ Because the requested preliminary injunction will preserve the status quo by preventing the loss of procedural rights in Japan, the requested injunction is not a "mandatory injunction" that would require Keryx to show a "clear" or "substantial" likelihood of success on the merits. See Sunward Electronics, Inc. v. McDonald, 362 F. 3d 17, 24-25 (2d Cir. 2004) ("The party seeking the injunction must show a 'clear' or 'substantial' likelihood of success where the injunction sought is mandatory – i.e., it will alter, rather than maintain, the status quo.") In any case, as demonstrated above, Keryx has more than met that heightened standard.

to several years.” (Arai Reply Decl. ¶ 5) Thus, Panion’s conduct in refusing to seek the routine and previously-agreed three-month extension will needlessly and irreparably sacrifice important procedural rights and expose Keryx to an unpredictable and likely prolonged delay in securing patent protection in Japan for the licensed Product. The threat of irreparable harm by Panion’s inexplicable conduct in breach of the License Agreement is undeniable.

Finally, the balance of hardships tips decidedly in Keryx’s favor. Absent the requested preliminary injunctive relief, an incomplete response will be submitted to the Japanese Patent Office. On the other hand, Panion has not asserted any cognizable harm that it would suffer from the requested injunction. Indeed, its opposition papers contain not a single word as to why preserving the opportunity for Keryx (and Panion) to properly respond to the Notice from the Japanese patent office would harm Panion.¹²

¹² Panion has not requested that Keryx post a bond under Rule 65(c), and none would be appropriate here in any case. See, e.g., Doctor’s Assoc., Inc. v. Distajo, 107 F.3d 126, 136 (2d Cir. 1997) (“Rule 65(c) gives the district court wide discretion to set the amount of a bond, and even to dispense with the bond requirement where there has been no proof of likelihood of harm . . .”) (quotations and citations omitted); Interlink Int’l Fin. Servs., Inc. v. Block, 145 F. Supp. 2d 312, 315 (S.D.N.Y. 2001) (“A district court may dispense with the posting of security entirely where parties sought to be enjoined or restrained have not shown that they will likely suffer harm absent the posting of a bond[.]”) (quotation and citation omitted) (Haight, J.).

CONCLUSION

The Court should grant Keryx's motion for a preliminary injunction.

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Respectfully submitted,

FRIED, FRANK, HARRIS, SHRIVER
& JACOBSON LLP

By: _____/s/
Gregg L. Weiner
Stephen S. Rabinowitz

One New York Plaza
New York, New York 10004-1980
(212) 859-8000

Attorneys for Plaintiff
Keryx Biopharmaceuticals, Inc.

559884